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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

HOBBS, MICHAEL L

ART UNIT

PAPER NUMBER

1797

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/527,958	<b>Applicant(s)</b> SIEBENKOTTEN ET AL.	
	<b>Examiner</b> MICHAEL HOBBS	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 September 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 38-44, 46, 47, 49-53, 55-57, 60, 61, 63-67, 69-76 and 79-81 is/are pending in the application.
- 4a) Of the above claim(s) 66, 67, 69-76 and 79-81 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 38-44, 46, 47, 49-53, 55-57, 60, 61 and 63-65 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>09/12/2005</u> .  | 6) <input type="checkbox"/> Other: _____                          |

**/DETAILED ACTION**

***Election/Restrictions***

1. Applicant's election with traverse of Group I claims 38-44, 46, 47, 49-53, 60, 61 and 63-65 in the reply filed on 09/19/2008 is acknowledged. The traversal is on the ground(s) that unity of invention is not lacking since US 4,441,972 does not disclose the special technical feature where a "reservoir[s] are separated from each other by a separating unit". This is not found persuasive because US 4,441,972 discloses the inner space, electrode and a reservoir that is connected to the inner space via an injector. This technical feature links the invention and does not provide a contribution over the prior art and no single general inventive concept exists.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 38-44, 46, 47, 49-53, 60, 61 and 63-65 are pending further examination upon the merits.

***Priority***

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claims 39 and 49 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. Regarding claims 39 and 49, the phrase "like" renders the claim(s) indefinite because the claim(s) include(s) elements not actually disclosed (those encompassed by "like"), thereby rendering the scope of the claim(s) unascertainable. See MPEP § 2173.05(d).

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 38, 41, 42, 44, 46 and 52 are rejected under 35 U.S.C. 102(b) as being anticipated by Schisselbauer (US 4,968,567) (hereafter referred to as Schisselbauer).

9. Regarding claim 38, Schisselbauer discloses an electrochemical cell that is sealed from the outside by a cap (cap 4) and includes an electrolyte reservoir (reservoir 2) which is fully capable of containing a biological material where the biological material is considered material worked upon by an apparatus and does not impart patentability to the claims (see MPEP 2115). Schisselbauer further includes a cell stack (stack 8) that includes a polarity electrode within the stack (col. 2 lines 24-27) and is within the cell stack chamber (chamber 10) which is being interpreted as the "inner space of the

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chamber". Also, Schisselbauer discloses a hole (hole 14) or inlet that is being interpreted as being disposed next to the cell stack (Fig. 1) and that the reservoir (reservoir 2) is formed by an internal wall (wall 12) and that the hole (hole 14) functions as the inlet line connecting the two interior spaces. Finally, the two interior spaces are separated by a rupturable diaphragm (diaphragm 16) that is broken by a lance (lance 18) which is activated by either manual activation or by an explosive device (col. 2 lines 16-19).

10. With regards to claims 41 and 42, the membrane of Schisselbauer is a rupturable diaphragm which read on a fragile membrane and the container is sealed and fully capable of being sealed in an aseptic manner. Regarding claim 44, the reservoir and chamber of Schisselbauer are connected to form one piece as shown in Figure 1 and for claim 46 the unit is fully capable of being sealed aseptically from the outside. Also, for claim 52, the reservoir is sealed by a cap (cap 4) which is being interpreted as "connected to an outlet opening".

11. Therefore, Schisselbauer meets the limitations of claims 38, 41, 42, 44, 46 and 52.

### ***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 39, 40 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schisselbauer in view of Berson et al. (US 6,720,178 B1) (hereafter referred to as Berson).

16. Schisselbauer discloses a hole or inlet connecting the two chambers, but is silent regarding the inlet being a tube.

17. Berson discloses a self-feeding bottle for culturing a cell where the bottle is divided into two compartments separated by a barrier (barrier 104). For claim 39,

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Berson discloses a tube (tube 116) that wraps around the outer perimeter of the reservoir chamber and pumps air and culture medium into the reaction chamber (col. 3 lines 51-53). Berson further discloses that the tube diameter can be either larger or smaller to adjust the flow rate from one chamber to the next (col. 3 lines 53-56). While not specifying a teaching to use the tube, a tube or "tube-like" shape as a conduit between two chambers, as shown by Berson, was known at the time of the instant application. Further, one of ordinary skill in the art would have been aware of a "tube-like" structure to connect chambers and as a flow restrictor and would have been able to modify the hole of Schisselbauer to be a tube in order to connect the two chambers. Therefore, under rationale B of *KSR*, 550 U.S. \_\_\_, 82 USPQ2d 1385m 1395-97(2007), it would have been obvious to one of ordinary skill in the art to try the tube of Berson to connect the two chambers of Schisselbauer to obtain the predictable result of moving fluid from the reservoir to the cell stacks.

18. With regards to claim 40, Schisselbauer and Berson are silent regarding the diameter of the tube decreasing as it approaches the electrode. However, as discussed above, Berson discloses that the tube diameter can be adjusted to control the volume of culture media entering the reaction chamber. Therefore, it would be obvious to one of ordinary skill in the art to modify the tube of Berson to have a decreasing diameter or taper to the tube as it approaches the proximity of the electrode of Schisselbauer. Therefore, it would be obvious to one of ordinary skill in the art to adjust the tube diameter in order to obtain the optimum diameter for the tube of the result effective

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variable in this known process, consult *In re Boesh and Slaney* (205 USPQ 215 (CCPA 1980)).

19. With regards to claim 43, Schisselbauer and Berson do not specifically state that the wall and reservoir are made from an elastic or deformable material. However, Berson discloses that the chambers can be made of polyethylene (col. 3 line 45) which is an elastic or deformable material. As a flexible or deformable material, polyethylene is known to have elastic properties and would have been obvious to one of ordinary skill in the art to employ as the wall and reservoir material of Schisselbauer.

20. Claims 50, 53, 55 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schisselbauer in view of Schwartzman (US 3,521,745) (hereafter referred to as Schwartzman).

21. Schisselbauer is silent regarding a chamber divided into several sub-units by at least one dividing member.

22. Schwartzman discloses a mixing chamber for storing two or three materials in different compartments where each compartment is separated or divided by membrane that is ruptured in order to mix the materials. For claims 50 and 55, Schwartzman divides the container up into three separate chambers (Fig. 1) and for claim 53 the cover (cover 16) is fully capable of holding the mixed materials thereby forming a single piece. Schwartzman uses the different chambers to hold three different materials such as dyes, cosmetics and medications that have an extended shelf-life when not mixed, but need to be used soon upon mixing (col. 1 lines 30-32 & 35-37). Therefore, it would



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be obvious to one of ordinary skill in the art to employ the membranes and cover as suggested by Schwartzman in order to hold the electrolytes and consequentially, the biological samples of Schisselbauer. The suggestion for doing so at the time would have been in order to mix and provide a convenient means for dispensing the fluid afterward (col. 1 lines 48-50).

23. For claim 60, the device of Schisselbauer is fully capable of being aseptically sealed from the outside.

24. Claims 51 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schisselbauer in view of Schwartzman and in further view of Berson.

25. Schisselbauer and Schwartzman are silent regarding the partition element being a valve.

26. For claims 51 and 56, Berson discloses that the partition element can be a valve (col. 6 lines 3-5; Fig. 4). The valve allows the reservoir to be shut-off from the growth chamber and removed without having to expose or open the growth chamber during processing (col. 3 lines 18-20). The implication of the valve in Berson means that the cell growth can be a continuous process with harvesting and replenishing the culture media can be handled without any undue exposure of the culture medium to the outside environment. Replacing the foil of Schisselbauer and Schwartzman with the valve of Berson would be obvious modification to one of ordinary skill in the art. Therefore, under rationale B of *KSR*, 550 U.S. \_\_\_, 82 USPQ2d 1385m 1395-97(2007), it would have been obvious to one of ordinary skill in the art to try the valve of Berson to connect

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the chambers of Schisselbauer and Schwartzman in order to obtain the predictable result of being able to control the flow of fluid to and from the separate chambers.

27. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schisselbauer in view of Blackburn (US 2003/0190608 A1) hereafter referred to as Blackburn).

28. Schisselbauer is silent regarding a chamber that has a serpentine or spiral shape.

29. Blackburn discloses a micro-fluidic device that has a mixing channel that for claim 49 has a serpentine shape ([0053]). This is a common shape for mixing channels and would have been known to one of ordinary skill in the art at the time of the invention. Furthermore, it would have been an obvious to one of ordinary skill in the art to modify the channel or hole of Schisselbauer to be a serpentine shape based on Blackburn in order to promote mixing within the channel with a reasonable expectation of success.

30. Claims 47, 57 and 61 rejected under 35 U.S.C. 103(a) as being unpatentable over Schisselbauer in view of Barbera-Guillem (US 2004/0029266 A1) (hereafter referred to as Barbera-Guillem).

31. Schisselbauer is silent regarding a wall that is self-sealing wall or septum that can be perforated.

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32. With regards to claims 47 and 57, Barbera-Guillem discloses a re-sealable elastomeric septum (septum 230) that permits the insertion of a small needle or pipette to load or remove a sample while maintaining the aseptic seal of the device and is part of the sidewall of the bioreactor ([0225]). Also, a septum or elastomeric wall is a known element within the art and solves the technical problem of allowing access to the interior of the chamber while preventing the chamber and interior samples from coming into contact with external contaminants. Furthermore, it would be an obvious modification to the device of Schisselbauer for one of ordinary skill in the art to allow a syringe or pipette to access the electrolyte (or biological sample) contained within the reservoir. Therefore, under rationale E of *KSR*, 550 U.S. at \_\_\_\_, 82 USPQ2d at 1397, it would have been obvious to one of ordinary skill in the art to employ the septum as suggested by Barbera-Guillem in order to access the interior chamber of Schisselbauer with a reasonable expectation of success.

33. For claim 61, it is an intrinsic property of the septum of Barbera-Guillem that the septum would be made of synthetic materials. It would be obvious to one of ordinary skill in the art for the reasoning used above.

34. Claim 63 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schisselbauer in view of Bean et al. (US 4,061,543).

35. Schisselbauer discloses a cell stack within the inner space and an electrode exterior to the cell stack, but is silent regarding an electrode pair within the inner stack.

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36. Bean discloses a cuvette for bioassays that includes an electrode pair within the cuvette. For claim 63, Bean discloses that the electrode pair (electrodes 11 & 12) which are "oppositely arranged" and are in contact with the inner space of the cuvette (Fig. 1). The electrodes within the cuvette (10) generate a controlled electric field in order to avoid mass transfer, electrode bubbling and electrode polarization (col. 2 lines 50-54). Modifying Schisselbauer based on the teachings of Bean would be obvious to one of ordinary skill in the art in order to generate an electric field within the inner chamber with a reasonable expectation of success.

37. Claims 64 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schisselbauer in view of Beichmann et al. (US 2002/0164776 A1).

38. Schisselbauer is silent regarding the material used for the electrodes.

39. Beichmann discloses a chamber for treating cell suspensions in an electric field where the electrodes are made of an electrically conductive material. For claims 64 and 65, Beichmann discloses that the materials are made from an electrically conductive plastic that have been metallized ([0025]). Since the combined teachings of Schisselbauer and Beichmann disclose the apparatus as claimed, the process for which it was made is the same as or obvious over the process utilized by Schisselbauer and Beichmann. It would be obvious to one of ordinary skill in the art to employ the plates as suggested by Beichmann in order to provide an electric field within Schisselbauer. The suggestion for doing so at the time would have been in order to have plates for which the cells or fusion products can be readily rinsed off ([0021]).

***Conclusion***

40. Claims 38-44, 46, 47, 49-53, 60, 61 and 63-65 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL HOBBS whose telephone number is (571)270-3724. The examiner can normally be reached on Monday-Thursday 7:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Beisner/  
Primary Examiner, Art Unit 1797

/M.L.H./

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